## REMARKS

Claims 1-14, 23, and 25-66 are pending in this application.

Applicants acknowledge the Office Action's rejection of the pending claims for alleged nonstatutory double patenting over U.S. Patent No. 5,780,497 and U.S. Patent No. 5,880,137. As this rejection is provisional in nature, Applicants will address this issue in a subsequent response upon indication of otherwise allowable subject matter in the present application.

Claims 1-6 and 55-66 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly being nonenabling. The Office Action states that the specification is enabling for the particular and specific pharmaceutical/active agent such as the compound of formula herein, in combination with a filler, disintegrant, wetting agent and a lubricant or a glidant in specific amounts herein formulated into a pharmaceutical composition herein. However, the Office Action alleges that the specification is not enabling for "**any** pharmaceutical agents having vaious and substantially different physical, chemical, and physiological properties ..." Office Action at page 3, emphasis original. Applicants respectfully disagree and assert that the claims are fully enabled by the specification.

The present claims recite formulations comprising specific percentages of one or more components, namely, a filler, disintegrant, wetting agent, lubricant and/or glidant. Thus, novel formulations are being claimed. Further, the claimed formulations may or may not include an active agent (e.g., claims 1). Moreover, the claimed formulations are fully enabled, and the Office Action has not established a basis for why the claimed formulations are not enabled.

To the extent that the Office Action is alleging that the claimed formulations are not enabled because the specification has only disclosed specific examples of active agents, Applicants respectfully assert that it is well settled law that everything necessary to practice the invention need not be disclosed in the specification. *In re Buchner*, 929

F.2d 660, 661 (Fed. Cir. 1991). In other words, the specification itself does not necessarily have to "describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments..." *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1244 (Fed. Cir. 2003). Thus, although the specification discloses a number of specific active agents for use with the claimed formulations, one of ordinary skill would be able to identify other suitable active agents for use in the formulation. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claim 34 stand rejected under 35 U.S.C. § 112, second paragraph, for alleged being indefinite. The Office Action states that claim 34 depends from claim 32. Claim 34 actually depends from claim 33 as recited. Moreover, claim 33 recites a range from about 20% to about 80%, which correctly covers the range of "from about 47% to about 77% lactose" of claim 34.

Claims 1-14, 23, and 25-66 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Miller et al. (5,780,497, or 5,880,137, or EP 0802184 A1, or EP 0802183 A1; collectively "Miller et al.") in view of Sawicka (Pharmazie 1991, vol. 46 page 519-521). Applicants respectfully traverse the rejection, as the cited art neither teaches nor suggests the subject matter of the pending claims.

The Office Action asserts that Miller et al.:

> ... teaches broadly a pharmaceutical carrier or excipient system in a pharmaceutical formulation comprising a filler and disentegrant components, a wetting agent, a lubricant, and a glidant including the instant preferred excipients such as lactose, microcrystalline cellulose, magnesium stearate and sulfate, and Miller et al. teaches that the preparation of the formulation comprising the instant compound in various oral forms with these well known excipients is **conventional** to an ordinary skilled artisan in pharmaceutical science.

The Office Action at page 8 and 9, emphasis original. Significantly, the Office Action admits that the prior art does not expressly disclose the claimed specific range amounts of a filler and disintegrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition, and also that the prior art does not expressly disclose the claimed pharmaceutical composition further comprising an antioxidant. The Office Acction nevertheless repeats its assertion that it would have been obvious:

> ...to determine the specific range amounts of a filler and disintegrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition herein.

Office Action at page 9. The Office Action bases its conclusion on an assertion that the components of the claimed formulations are known in the art, and that the determination and optimization of amounts of such components are considered conventional, relying on *In re Boesch*, 205 USPQ 215 (CCPA 1980).

As best understood, the Office Action appears to assert that where compounds and formulation ingredients are known in the art then, *a priori,* any formulation developed therefrom is *prima facie* obvious under *In re Boesch*, which, according to the Office Action, holds that it is within the skill in the art to select optimal parameters, such as the amount of ingredients, in order to achieve a beneficial effect. However, the court in *In re Boesch* upheld the Board's finding of Applicant's invention to be *prima facie* obvious, at least in part, because the ranges of Applicant's claimed invention overlapped with those of the prior art. See *In re Boesch*, at 218 ("The board agreed with the examiner that the claimed alloys were prima facie obvious from the prior art, noting that there was no substantial disagreement that both Pohlman et al. and Lamb disclose alloys *having compositional limits overlapping those of the claimed alloys*.") (emphasis added).

The facts of *In re Boesch* stand in stark contrast to the present application wherein a large number of possible parameters that may or may not affect the outcome must be correctly chosen, discarded or optimized without the guidance of any given ranges or other teachings from the art itself.[1] The Office Action appears to premise its argument on an assertion that it would be obvious for one of ordinary skill in the art to vary every possible parameter (and combinations of parameters) of a system in order to optimize the effectiveness of the system; even where there is no evidence in the record that any given parameter would affect the result. However, the Office Action has not pointed to any legally sufficient motivation to modify the cited art either by making the claimed selections of components, or by employing the claimed ranges of those components. At best, the Office Action has employed an "obvious to try" analysis, which is not a permissible basis for a rejection under 35 U.S.C. §103. *In re Geiger*, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987).

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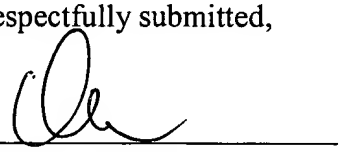
[1] The Office Action asserts on page 8 and 9 that Miller et al. "teaches broadly a pharmaceutical carrier or excipient system in a pharmaceutical formulation comprising a filler and disentegrant components, a wetting agent, a lubricant, and a glidant..., and Miller et al. teaches that the preparation of the formulation comprising the instant compound in various oral forms with these well known excipients is **conventional** to an ordinary skilled artisan in pharmaceutical science." However, Applicants do not find any support for the assertion in the cited art. The only references to conventional with regard to formulation in Miller et al can be seen, for example, in US 5,880,137 column 7, lines 28-31 ("Oral formulations containing the active compounds of this invention may comprise any *conventionally* (ital. added) used oral forms, including tablets, capsules, buccal forms troches, lozenges and oral liquids, suspensions, or solutions" and in US 5,880,137 column 7, lines 37-38 ("Useful tablet formulations may be made by *conventional* (ital. added) compression, wet granulation or dry granulation..."). Neither of these terms can be read as supporting the Office Action's position as quoted from page 9 of the office action.

Accordingly, the cited art, alone or in combination, does not render the present claims obvious. In view of the foregoing, Applicants assert that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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